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(71) Applicant *(for all designated States except US)*: ASTRA AKTIEBOLAG [SE/SE]; S-151 85 Södertälje (SE).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: NYQVIST-MAYER, Adela [SE/SE]; Eklidsvägen 20, S-146 40 Tullinge (SE). WALTER, Peter [DE/DE]; Rathausgasse 6, D-63683 Ortenberg 5 (DE).

(74) Agent: ASTRA AKTIEBOLAG; Patent Dept., S-151 85 Södertälje (SE).

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Published

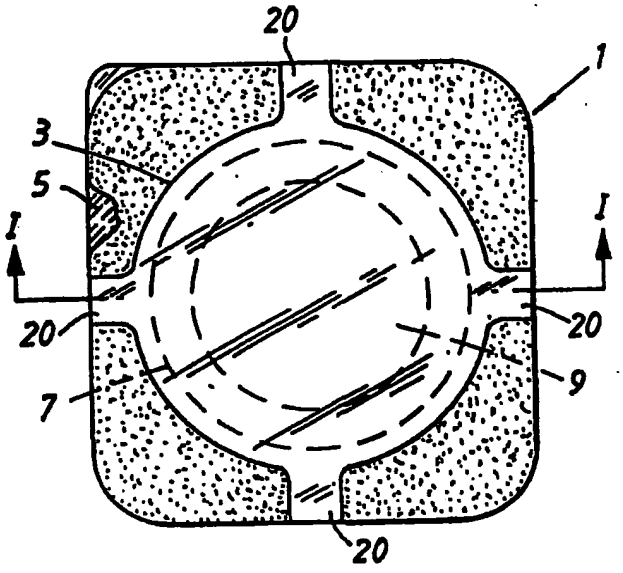
With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: A TOPICAL DRESSING, METHOD OF MANUFACTURING A TOPICAL DRESSING AND USE OF A TOPICAL DRESSING

(57) Abstract

A topical dressing for dermal or transdermal administration of a substance, comprising a backing structure (1) comprising a disc (3), a pad (9) containing the active substance, a resilient layer (4) with an adhesive (5) provided on one side thereof, the resilient layer and the adhesive being provided with a cut-out (7) defining a cavity (8) in which the pad (9) is placed, the disc (3) of the backing structure (1) being provided on the side of the resilient layer remote from the side provided with the adhesive and partly covering the resilient layer (4), and a covering structure (2) having a release liner and a dish (18), the dish being formed to receive the pad (9) during production and storage of the dressing, said covering structure (2) being provided on the adhesive side of the resilient layer (4), whereby the backing structure (1) is provided with one or more strips (20) extending outwardly from the periphery edge of the backing disc (3) towards the periphery edges of the resilient layer (4) and the cover structure (2) and the backing structure (1) are sealed together within the cavity (8). There is also provided a method of producing a topical dressing according to the invention and a suggested use of the same topical dressing.



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A topical dressing, method of manufacturing a topical dressing and use of a topical dressing.

Field of the invention

The invention is related to a topical dressing for dermal or transdermal administration of a substance, comprising the features of the preamble of claim 1.

The invention is also related to a method of manufacturing the topical dressing for dermal or transdermal administration according to the invention.

Background of the invention

This invention relates to dressings for use in the topical administration of drugs and other substances.

It is known to administer drugs dermally and transdermally i.e. by maintaining a drug in intimate contact with a patients skin so that the active constituent slowly passes into and through the skin and is absorbed into the patient's body over a prolonged period of time.

The drug is usually held in position for the requisite period of time using an adhesive patch.

EP-A-0013606 describes an adhesive patch for transdermal drug administration which comprises a laminated backing strip shaped to provide a cavity which is filled with a polymeric matrix containing the drug to be administered. The cavity is bounded with skin adhesive and is sealed by a laminated cover strip which is held in position by the adhesive. The cover strip is provided with a surface layer of release material so that it can be readily separated from the backing strip to

expose the polymeric diffusion matrix and the skin adhesive for use.

EP-B-0181333 describes an adhesive patch for transdermal administration which comprises a backing strip having a ring of microporous material fixed to a support sheet which is a polyethylene/metal foil/polyester laminate. The ring of microporous material has a surface layer of skin adhesive and defines a central cavity which contains the drug to be administered. A cover strip is formed from the same laminated material as the above mentioned support sheet and is held in position to seal the cavity by engagement of a release layer on the surface of the cover strip with the skin adhesive, and by means of a heat seal ring between the laminated materials of the backing strip and the cover strip beyond the outer periphery of the ring of microporous material. The drug in the cavity and the skin adhesive are exposed for use by separating a portion of the lamination material of the backing strip with the attached ring of microporous material by tearing the laminated material around a ring of perforations.

With the above mentioned known constructions sealing of the cavity is achieved by virtue of the engagement between the layer skin adhesive on the backing strip and the release layer on the cover strip, and in the case of EP-B-0181333 also by means of the outer heat seal ring. With this arrangement there is the problem that the drug in the cavity may at least partially escape, e.g. by diffusion into the surrounding adhesive and/or other layers, especially if the drug is of a mobile or volatile nature, and particularly if the drug is present in the cavity by itself or absorbed on a pad or otherwise in readily releasable form rather than being incorporated in a rotentive medium such as the polymeric matrix of EP-A-0013606. Since transdermal dressings may be used for accurate administration of predetermined quantities of drugs it will be appreciated that escape of quantities of the drug from the cavity can constitute a serious problem.

A topical dressing of the above mentioned type is also described in Australian

Patent Application No. 75975/91. This dressing is provided with a backing layer which contains a backing sheet which only partly covers the resilient layer and having the features of the preamble of claim 1.

In the above mentioned Australian dokument the backing sheet is provided as single pieces of backing which, during production, are intended to be placed, one by one, on the continuous layer of resilient material at predetermined positions. This is a procedure which however gives raise to a new problem. Because the backing sheet is made of a very thin material, about 10 - 50 μm, the edges of the pieces of backing will bend upwards which makes the application of the discs on the resilient structure more difficult and, under certain circumstances, almost impossible. Even if the disc is placed properly on to the resilient structure the sealing between the disc and the resilient structure might be negatively influenced and leakage could occur during use of the patch.

The most obvious way to solve this problem is to provide the backing disc or sheet as a continuous layer covering the whole continuous layer of resilient material. This will however provide a non-flexible dressing which would be difficult to apply on several parts of the body such as elbows, knees, hands etc. It would also create a significant discomfort for the user. Therefore the backing sheet has to be smaller than the resilient material in the final patch.

It is therefore necessary to solve this problem without deteriorate the flexibility of the final product.

<u>The invention</u>

It is therefore an object of the present invention to provide a topical dressing of the above mentioned type which overcomes the drawbacks with the known

dressings and which provides a dressing which adheres properly to the skin of the user without leakage of the active substance and which is easy to apply and comfortable for the user when dispatched on the skin. It is also simple and convenient to manufacture and which can be readily unsealed when required for application to the skin.

This is achieved by providing the backing structure with strips extending outwardly from the periphery edge of the backing disc towards the periphery edges of the resilient layer, as described in the characterising portion of claim 1.

Further preferred embodiments are described in the dependent claims 2 to 4.

It is also an object of the present invention to provide a method of manufacturing a topical dressing for transdermal administration as described in claim 5, as well as a use of the topical dressing according to the invention for transdermal administration af an active substance as described in claims 9 and 10.

Further preferred steps are described in the dependent claims 5 to 8.

Brief description of the drawings

The topical dressing according to the present invention will now be described by way of example with reference to the appended drawings, wherein

Fig. 1 is a sectional view of the preferred embodiment of the dressing according to the invention, taken along lines I-I in fig. 3,

Fig. 2 is a face view of the of cover structure of the dressing in Fig. 1,

Fig. 3 is a face view of the of backing structure of the dressing in Fig. 1,

Fig. 4 is a diagrammatic illustration of a method of manufacturing the dressing.

Detailed description of the drawings

The dressing is now described in relation to a preferred embodiment of the dressing according to the invention.

The dressing has a backing structure 1 and a cover structure 2, as can be seen in Fig. 1 to 3.

The backing structure 1 comprises a disc 3 which is preferably, but not necessarily, circular and made of impermeable material, e.g. a laminate such as for example a metal foil coated on opposite sides with polymer layers. One side of the laminate or one of the polymer layers is fixed centrally to a layer 4 of resilient material, such as for example plastic foam material. The resilient foam material is coated with a layer 5 of an adhesive which adheres to the skin of a user.

The covering structure is made of an impermeable material, e.g. a laminate such as for example a metal foil coated on one side with a polymer layer. In the preferred embodiment of the invention the covering structure is made of a metal foil which is thicker and more rigid than the material of the backing structure. This covering structure provides a support for the dressing in order to prevent deformation of the dressing and leakage of the active substance during storage and handling.

In order to prevent the bending up of the edges of the disc 3, when it is placed on the resilient layer during the manufacture process, the disc 3 is provided with

reinforcing strips 20. These strips 20 are preferably, but not necessarily, four and extending from the periphery edge of the disc 3 outwardly to the periphery edges of the resilient layer 4 and provided along the periphery of the disc 3 in preferably, but not necessarily, about 90° relation to each other, see Fig. 3. The strips 20 are of the same material as the disc 3 and fixed to the resilient layer 4. The size of the strips 20 is determined by the distance between the periphery edge of the disc 3 and the periphery edges of the resilient material 4. Tests have shown that best result, that is a total elimination of the "bending up-effect" is achieved when the strips 20 are positioned centrally along the sides of the resilient layer 4 as can be seen in Fig. 2. The strips 20 must have a certain sideward extension, eg. a certain breadth, for the wanted effect to be achieved but it must be as small as possible in order to not significantly deteriorate the resiliency of the resilient layer 4. In the preferred embodiment the breadth of the strips 20 is about 5 to 20%, preferably about 10%, of the total length of the sides of the resilient layer.

The disc 3 is centrally fixed to the resilient layer 4. The resilient layer 4 has a centrally provided substantially circular cut-out 7. The entire surface of the resilient layer is coated with the adhesive 5 and the centrally provided cut-out is totally free from such adhesive.

A cavity 8 is defined within the cut-out 7 and a disc-shaped pad 9 of a porous material is placed within the cavity 8. The thickness of the pad 9 is slightly thicker than the thickness of the resilient layer 4. The pad is located centrally in the cavity and has a diameter which is smaller than the diameter of the cut-out 7 so that an annular space 10 is defined therebetween. The pad is fixed to the disc 3 in any suitable manner such as for example heat sealing.

The cover structure 2 comprises a disc 12 of impermeable material such as a metal foil coated on both sides with polymer layers. One side of the disc 12 is fixed to a sheet of a release liner 13 and the disc 12 could be fixed to the release liner 13 by

a circular heat seal. The release liner 13 is provided with a central cut-out 15 having the same size as the cut-out 7 in the resilient layer 4.

The cover structure 2 is applied to the backing structure 1 so that the liner 13 is in aligned superimposed relationship with the adhesive-coated resilient layer 4 and the two structures 1 and 2 are held together by the adhesive 5 and a seal between the discs 3 and 12.

The central circular portion 16 of the disc 12 is formed so that a substantially circular ridge 17 is provided thereby defining a dish 18. The form of the ridge 17 is chosen so that it will be placed within the confines of the cut-out 15 in the release liner 13 and resilient layer 4 when the cover structure 2 and the backing structure 1 are joined together. In this position the ridge 17 will project through the two cut-outs 15 and 7 into engagement with the disc 3. The ridge 17 is heat sealed to the disc 3.

The active substance intended to be dermally and transdermally administered by the use of the dressing according to the invention is absorbed in the pad 9. The pad is made of a porous material, preferably cellulose-material.

Examples of active substances which can be dermally and transdermally administered by using a topical dressing according to the invention are local anaesthetics, such as EMLA®, analgesics, steroids, nicotine, antibiotics.

Due to the preferred construction of the dressing the active substance is wholly sealed between the disc 3 and the disc 12 whereby there is no possibility that the substance could escape into adjacent layers.

When the dressing is to be used the covering structure 2 is peeled off whereby it separates from the adhesive layer 5 at the release liner 13 and the ridge 17 pulls

away from the disc 3 rupturing the seal therebetween. The dressing can then be applied to the skin so that the adhesive layer 5 holds the dressing in position with the pad 9 in contact with the skin.

The topical dressing according to the invention can be readily filled and securely closed, and advantageous manufacture can be achieved on a mass production basis whilst ensuring adequate levels of hygiene and security. Moreover, the resulting dressing is particularly convenient to use and effective medication can be achieved whilst avoiding escape of substances likely to contaminate clothing and be uncomfortable for the patient.

The dressing described above can be manufactured by using a method as described below with reference to Fig. 4.

The impermeable laminate of the covering structure is prefabricated and provided as a first continuous elongated sheet 21 on a first roller 22. The ridge 17 is formed in first sheet 21 in a stamping station 23 thereby providing a dish 18.

The resilient layer 4 with the adhesive 5 and the release liner 13 is supplied as a second continuous elongated sheet 41 from a second roller 42 and the cut-outs 7 are provided in a cutting station 43. The cut-outs defines the cavities 8 in the resilient structure. After the cutting this second elongate sheet 41 is placed on top of the laminate of the covering structure, e.g. the first sheet 21 and fixed thereto, preferably by heat sealing.

In a parallel production line the backing structure 1 is manufactured. The impermeable laminate of the backing structure is prefabricated and supplied as a continous elongate sheet 51 and provided on a third roller 52.
Thereafter the pads 9 which have been prefabricated are applied from colons 91,

placed on the backing sheet and sealed to it in a sealing station 92. The active substance is thereafter applied to the pads 9 at the filling station 93. According to the above it is preferred to apply the active substance pads after they have been placed and sealed to backing sheet but it is also possible to apply the active substance before the step of placing and sealing.

After the filling of the pads the elongate sheet 51 is passed on to a cutting station 53. Here the parts of the material of the laminate which do not form part of the disc 3 and the strips 20 are cut away in such a manner that the backing material is still kept as an elongate sheet whereby strips provided on adjacent discs are connected to each other. Hereby the bend-up of the edges of the discs is avoided which, as described above, facilitates the handling and manufacture significantly.

In the next step the continuous elongate sheet of discs 3 and strips 20, with the pads 9, is turned upside-down and placed on top of the resilient layer 4 as can be seen in fig. 4. The pads 9 are thereby placed within the dish 18 defined by the ridge 17. Thereafter the resilient layer 4 and the covering 2 on the one hand and the backing disc 3 and the ridge 17 on the other hand are fixed together, preferably by using heat sealing, at a sealing station 55. Circular heat sealing rings 6 are thereby provided surrounding the cavity 8, the ridge 17, the dish 18 with the pad 9 and the cut-outs 7.

The continuous sheet of dressings which is the result of the above described method is cut in a cutting station 56 in order to provide the single pieces of dressings.

Possible modifications of the invention

The dressing and the manufacturing method according to the invention could of

course be modified within the scope of the appended claims.

Thus, the materials chosen above can be changed as well as the form and sizes of the different parts. In particular the cut-outs and the disc of the backing structure must not necessarily be circular but could have any other suitable form, such as being oval, quadratic or rectangular. The strips 20 could be provided differently around the periphery of the disc of the backing structure and could have different forms. It is however important to avoid the bend-up effect of the edges of the disc during the manufacture of the dressing. The backing structure must be flexible but at the same time provide a impermeable backing support for the active agent.

The backing structure and the covering structure may be formed from the same or different materials, preferably a metal foil/polymer laminate but any other material having similar characteristics may be used. The polymer content of the laminate may be polyethylene, polypropylene, polyester, ionomer.

The working stations as well as the steps of the manufacturing line can also be modified within the scope of the appended claims

Claims

1. A topical dressing for dermal or transdermal administration of a substance, comprising a backing structure (1) comprising a disc (3), a pad (9) containing the active substance, a resilient layer (4) with an adhesive (5) provided on one side thereof, the resilient layer and the adhesive being provided with a cut-out (7) defining a cavity (8) in which the pad (9) is placed, the disc (3) of the backing structure (1) being provided on the side of the resilient layer remote from the side provided with the adhesive and partly covering the resilient layer (4), and a covering structure (2) having a release liner and a dish (18), the dish being formed to receive the pad (9) during production and storage of the dressing, said covering structure (2) being provided on the adhesive side of the resilient layer (4), c h a r a c t e r i s e d in that the backing structure (1) is provided with one or more strips (20) extending outwardly from the periphery edge of the backing disc (3) towards the periphery edges of the resilient layer (4) and in that the cover structure (2) and the backing structure (1) are sealed together within the cavity (8).

2. Topical dressing according to claim 1, c h a r a c t e r i s e d in that the strips (20) are preferably four and provided along the periphery of the disc 3 in about 90° relation to each other.

3. Topical dressing according to claim 1, c h a r a c t e r i s e d in that the strips (20) are made of the same material and cut out from a continuous elongate sheet (51) but connected to the disc (3) thereby providing a continuous elongate sheet.

4. Topical dressing according to any of the preceding claims, c h a r a c t e r i s e d in that the covering structure (2) comprises a

covering disc (12) having a ridge (17), defining a dish (18), and a release liner (13), whereby the ridge (17) overlays the cavity (8) with the pad (9) and is held in contact with the backing disc (3) between the pad (9) and the surrounding resilient layer (4) thereby defining a seal around the pad with the substance.

5. Method of manufacturing a topical dressing comprising the steps of:

- supplying a first continuous elongate sheet (21) of an impermeable material,
- stamping out a ridge (17) in the first sheet (21),
- providing a second continuous elongate sheet (41) of a resilient layer (4), having an adhesive (5) provided on one side and a release liner (13) provided on the adhesive (5) and having cut-outs (7), on to the first sheet (21) in such a manner that the side of the resilient layer (4) which is provided with the adhesive (5) and the release liner (13) is placed on to the first sheet (21) and so that the cut-outs (7) of the resilient layer (4) and the release liner (13) respectively and the ridge (17) of the first sheet (21) being in aligned superimposed relationship with each other thereby defining the cavities (8),
- supplying a third continuous elongate sheet (51) of an impermeable, preferably prefabricated, backing structure (1) of an material,
- supplying pads (9) of a porous material to the third sheet (51),
- cutting away part of the material of the third sheet (51) thereby providing a continous elongate sheet of backing,
- placing said continous elongate sheet of backing, with the pads (9), on top of the resilient layer (4) thereby covering the cavities (8) and partly covering the resilient layer (4), whereby the pads (9) will be provided within the ridge (17),
- cutting the continuous sheet of dressings to provide single topical dressings of the type described in claims 1 to 4.

6. Method according to claim 5, wherein the backing structure is formed, during the cut-away of material, as discs (3) with strips (20) and wherein the discs (3) are preferably substantially circular or oval, and the strips (20) extend outwardly from the periphery edge of the disc (3).

7. Method according to claim 6, wherein the strips (20) and the discs (3) are manufactured from a continuous elongate sheet of impermeable film of flexible material by cutting away the pieces of the material which are not a part of the end product, whereby the strips (20) connect the discs (3) to each other during manufacture and form a continuous layer of the backing material.

8. Method according to claim 6, wherein the strips (20) are four and arranged along the periphery of the backing disc (3) at an angle of substantially 90° in respect of each other.

9. Method according to claim 5, wherein the active substance is applied to the pads (9) before the pads are placed on the backing structure (1).

10. Method according to claim 5, wherein the active substance is applied to the pads (9) after the pads have been placed on and sealed to the backing discs (3).

11. Use of a topical dressing according to claim 1 for dermal or transdermal administration of an active substance.

12. Use according to claim 11, wherein the active substance is a local anaesthetic.

13. Use according to claim 12, wherein the active substance is EMLA®.

Fig. 1

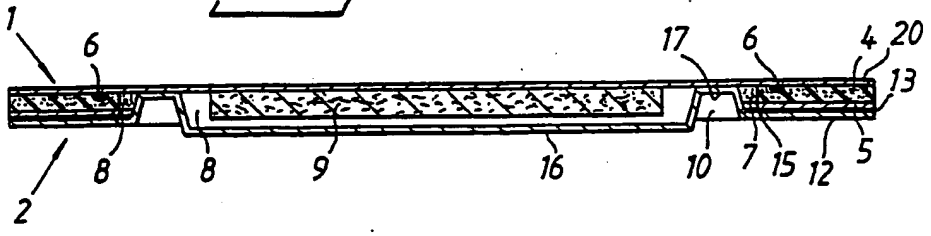


Fig. 2

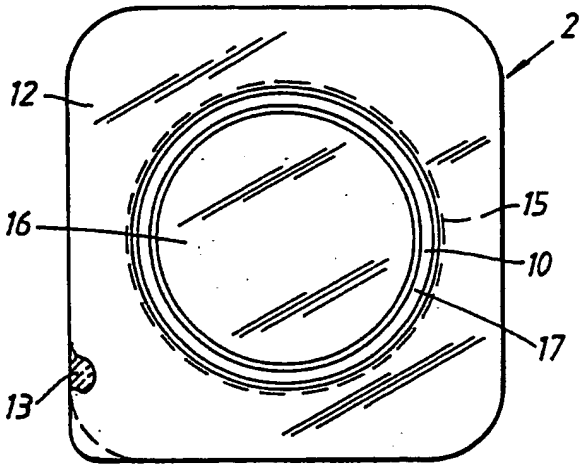
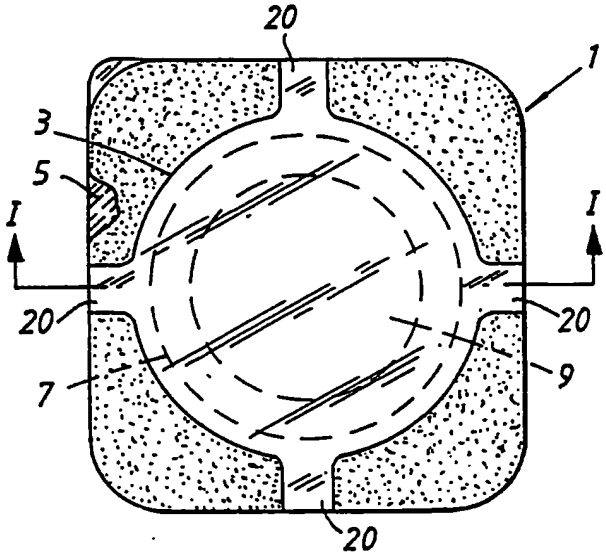


Fig. 3



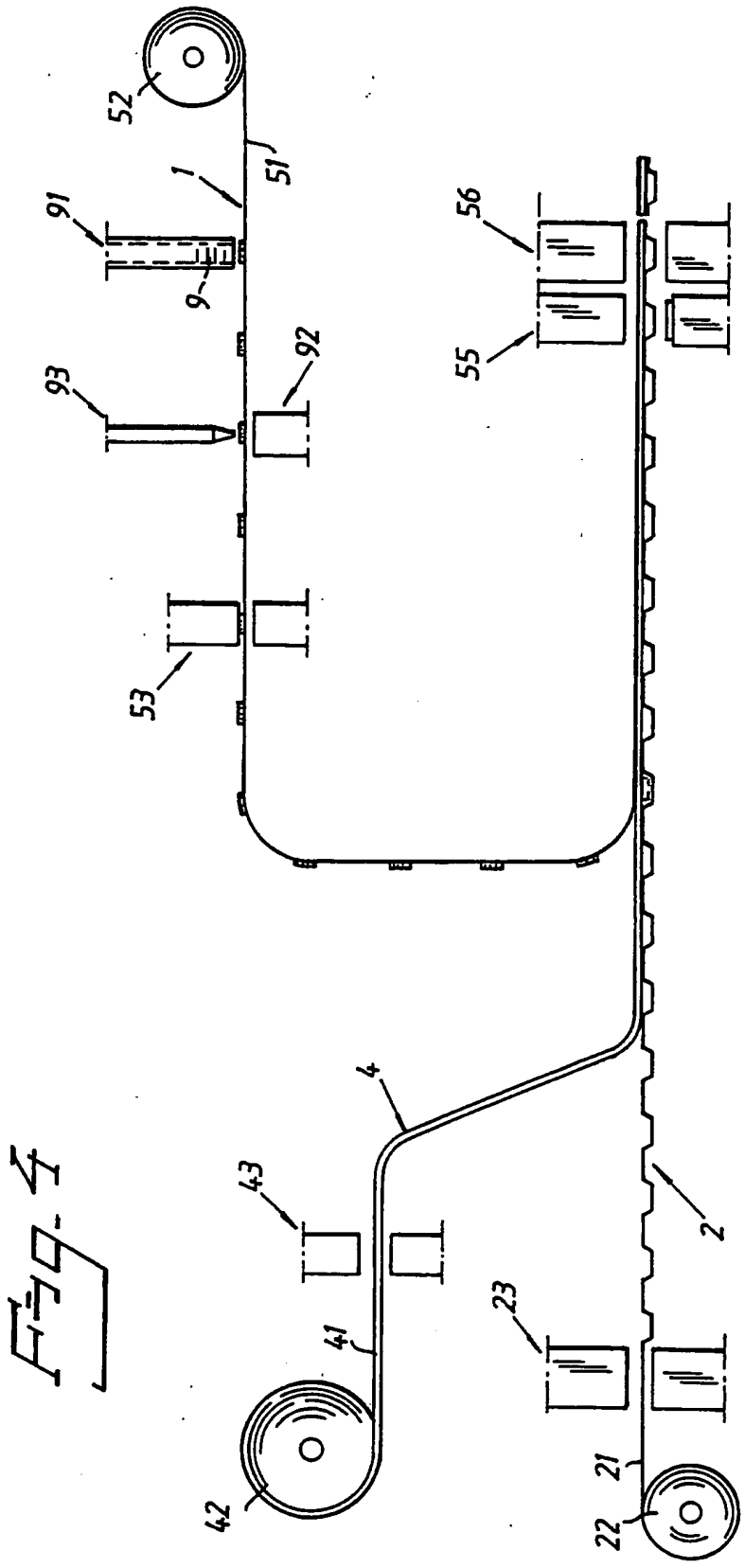


Fig. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 95/00368

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 35/00 // A61F 13/02
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61F, A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	NO 163438 B (ALLPACK INDUSTRIELLE LOHNVERPACKUNG GMBH & CO. KG), 19 February 1990 (19.02.90) --	1,5
A	DE 3204582 A1 (HASSIA VERPACKUNG GMBH), 25 August 1983 (25.08.83) --	1,5,10
A	AU 646453 B (AB ASTRA), 26 November 1992 (26.11.92) --	1,4,5
A	US 3900027 A (KEEDWELL), 19 August 1975 (19.08.75) --	5,10

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 July 1995	01 -08- 1995
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Leif Vingård Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 95/00368

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4915102 A (KWIATEK ET AL), 10 April 1990 (10.04.90) --	1,4,5
A	US 5268179 A (RUDELLA), 7 December 1993 (07.12.93) --	5
A	WO 8500287 A1 (HARLANDS OF HULL LIMITED ET AL), 31 January 1985 (31.01.85) --	1,5,10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 95/00368

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Use of a medical device, which is considered equivalent to the kind of methods stated in PCT Rule 39.1(iv).

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

A topical dressing according to claims 1-4, and a method of manufacturing of a topical dressing according to claims 5-10 which method is not limited to the topical dressing according to claims 1-4.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT
Information on patent family members

29/05/95

International application No.
PCT/SE 95/00368

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
NO-B- 163438	19/02/90	NONE	
DE-A1- 3204582	25/08/83	NONE	
AU-B- 646453	26/11/92	NONE	
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US-A- 4915102	10/04/90	EP-A,A,A 0356614	07/03/90
		JP-A- 2068059	07/03/90
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		CA-A- 2089468	15/08/93
		EP-A- 0556158	18/08/93
		JP-A- 5255076	05/10/93
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		CA-A- 1232806	16/02/88
		EP-A,B- 0181333	21/05/86
		SE-T3- 0181333	
		US-A- 4687476	18/08/87